

## REMARKS

Reconsideration is respectfully requested in view of the foregoing amendments and the remarks which follow.

By this amendment, Applicant has amended claims 50-52, 57, 60, and 64-70. The amendments made to the claims are fully supported in the as-filed specification.

5 It is respectfully submitted that the objection to claims 50,58-60 and 64-70 should be withdrawn in view of the amendments made herein.

New claims 66-69, which were added by the amendment filed on December 12, 2005, did not include the terms "polyphenolic" and "hydrophilic".

10 The term "inactivated microorganism" which appears in claims 50, 51, 58, 59, and 66-70 has been amended to read "microorganism's cell wall". This term is fully supported in the as-filed specification.

Claims 50 and 58 have been amended to delete "or a mixture thereof".

Claim 60 has been amended to clarify that the "microbial cell with or in a hypertonic solution" comprising NaCl.

15 At line 1 of claims 64 and 65, Applicant has inserted a -- , -- after the word "wherein".

Accordingly, the foregoing objections to the claims have been overcome and should be withdrawn.

20 The Examiner has rejected claims 50-70 under §112, second paragraph, for indefiniteness. Applicant respectfully traverses this rejection. The Applicant has amended claims 50 (iii) and claims 51, 58, 59 and 66-70 to recite-- microorganism's cell wall --, in lieu of the terms "inactivated microorganism" or "microorganism".

Claim 52 has been amended to delete the recitation of the term "suitable".

Claim 57 has been amended to delete the parentheses.

Claims 66-70 have been amended to recite -- obtained --. The term "obtainable" has been deleted.

Since the rejection under §112, second paragraph, has been overcome, the rejection  
5 should be withdrawn.

The Examiner has rejected claims 50-70 under §103(a) as obvious over the combined teachings of Pannell U.S. 5,288,632 in view of Sagar et al., (WO 94/22572). This rejection is respectfully traversed.

Steps (i) and (ii) of independent process claim 50 are critical to the claimed  
10 process. They are essential and distinct steps in the process. The end result of these two process steps is a microorganism's cell wall which has been freed of its endocellular contents. Stated in other words, the net result is an empty cell wall, which is ready to be filled or loaded in step (iii) with pharmaceutically active substances.

The primary reference relied upon by the Examiner, Pannell neither teaches,  
15 suggests, nor even intimates a hypertonic treatment followed by separation and removal of the endocellular mass and the recovery of the microorganism's cell wall.

The Sagar reference employed by the Examiner does not provide any teaching of the method claimed herein nor does it disclose or introduce the above-referenced steps, i.e., hypertonic treatment followed by separation of the endocellular mass, into the process  
20 for the preparation of microorganisms.

The Pannell reference only describes a process where the microorganism is placed directly into contact with the solution containing the active substance. The foregoing is evident by reference to column 2, lines 26-40 of Pannell which makes it abundantly clear that the microorganism is treated directly with the solution comprising the

“encapsulatable material” and that no preliminary “*hypertonic treatment*” is even intimated or suggested, much less disclosed.

Sagar, as pointed out previously, is completely and utterly silent about a preliminary treatment with a hypertonic solution. Therefore, there is no suggestion or  
5 motivation to introduce this step. It is, in other words, completely lacking in both Pannell and Sagar.

In point of fact, the only place where treatment with a hypertonic solution is disclosed is Applicant’s own specification. Hindsight reconstruction of the prior art based only upon Applicant’s disclosure cannot provide the basis for a §103(a) rejection.

10 From a careful reading of Item 10 in the current Office Action, it is to be noted that the Examiner never even mentions that either of the references teach a “hypertonic treatment”. By contrast, in Applicant’s claimed process, the *hypertonic treatment* is essential. The benefits to be realized from the hypertonic treatment are that the microorganism is completely emptied while leaving the cell wall and membrane intact and  
15 unaltered, allowing it to be filled with the pharmaceutical substance.

The Examiner’s statement that Pannell intrinsically teaches removing the endocellular material, is not a teaching upon which the Examiner can rely to sustain an obviousness rejection herein. There simply is no teaching or suggestion in Pannell that would lead one of ordinary skill in the art to remove the endocellular material for treatment  
20 with a hypertonic solution. Neither does the secondary reference, Sagar, ameliorate this glaring deficiency in the teaching of Pannell.

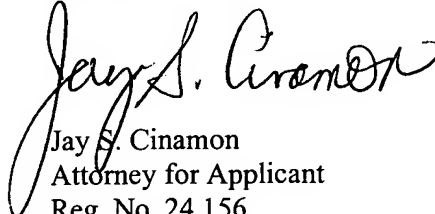
It is respectfully submitted that the Examiner has not established a *prima facie* case of obviousness, and that the claims herein distinguish over the references applied by the Examiner. Accordingly, the §103 rejection has been overcome and should be withdrawn.

Since the objections and rejections of record have been overcome a Notice of Allowance is respectfully solicited.

Please charge any other fees which may be due, and which have not been submitted herewith, to our Deposit Account No. 01-0035.

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Respectfully submitted,

  
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